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| 10/532,698 | 04/26/2005 | Nicolai Agger | P07181US00 | 8742 |

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| EXAMINER | |
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| CLARK, AMY LYNN | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1655 | |

DATE MAILED: 11/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/532,698 | AGGER, NICOLAI | |
| | Examiner | Art Unit | |
| | Amy L. Clark | 1655 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *12 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *12 and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11, 13-23 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/26/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election without traverse of the composition of Claims 1-22 in the reply filed on 12 October 2006 is acknowledged.

Claims 1-25 are currently pending.

Claims 12 and 24 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12 October 2006.

**Claims 1-11, 13-23 and 25 are under examination.**

### *Specification*

The abstract of the disclosure is objected to because therapeutical" should be changed to therapeutic, the spelling of the word "diarrhoea" should be changed to diarrhea, and the composition recited in the Abstract should be changed to reflect the changes made under the 112 2nd paragraph rejection below, see rejection of claim 1 under the heading "*Claim Rejections - 35 USC § 112*". Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities: in all cases, the spelling of the word "diarrhoea" should be changed to diarrhea, the spelling of the word "colouring" should be changed to coloring, and the spelling of the word "alfa-toferol" should be changed to alpha-tocopherol.

Appropriate correction is required.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: "Composition comprising Isphagula husk (Latin name), an amino acid, a carbohydrate and electrolytes for (insert the intended use here. Please note that nowhere in the composition claims, as written, is "gastrointestinal disorders" mentioned. Please add "therapeutic agent" as intended use to the title since that is how the claims currently read)".

***Claim Objections***

Claim 1 is objected to because of the following informalities: "therapeutical" should be changed to therapeutic in line 4. Appropriate correction is required.

Claim 13 is objected to because of the following informalities: change the spelling of "diarrhoea" in line 3 to diarrhea (please also change the spelling of "diarrhoea" to diarrhea when amending all claims that contains this word, such as the use claims of 2-4 and 25). Appropriate correction is required.

Claims 17, 21 and 22 are objected to because of the following informalities: change the spelling of "colouring" in line 2 of Claim 17 and Claim 21 and of line 1 in Claim 22 to coloring. The word --and--should be inserted between "corrigent" and "at least one coloring agent" in line 2 of Claim 17. Appropriate correction is required.

Claim 23 is objected to because of the following informalities: "alfa-toferol" is misspelled (See lines 1 and 2). The correct spelling is alpha-tocopherol. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-4 and 25 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 and 14-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of Claims 1-5 are uncertain because it is unclear as to the identification of the ingredients to which Applicant intends to direct the subject matter. Although the use of common names or traditional/ethanopharmacological names is permissible in patent applications, the standard Latin genus-species name of each ingredient should accompany non-technical nomenclature as a means for identifying the subject botanical as noted in this application. The common name or traditional/ethanopharmacological name may have several different Latin names referring to various genus-species of the plant and it is unclear as to which genus and

species Applicant is referring. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired. Applicant may overcome the rejection by placing the genus-species name of "Isphagula" in parentheses after the term "Isphagula". Please be sure to write the Latin name in italics.

The metes and bounds of Claims 1, 9, 11 and 13 are uncertain because it is unclear as to what Applicant means by the following "from 20-80% by weight of at least one carbohydrate and electrolytes for use as a therapeutical agent" in Claim 1, lines 4 and 5, "wherein the at least one amino acid is comprised in the soluble components of lactic yeast" in Claim 9, line 2 and "wherein the amino acid is glutamine and is in the range of up to 10% by weight" in Claim 11, lines 1 and 2, and " wherein at least one of the salts comprised by the electrolytes and is at least one of the salts which will replace at least one of the salts lost by diarrhea" in Claim 13, lines 1-3 because it is unclear as to what Applicant is claiming. In claim 1, where Applicant claims "from 20-80% by weight of at least one carbohydrate and electrolytes for use as a therapeutical agent" in lines 4 and 5, it is unclear is Applicant is claiming 20-80% by weight of at least on carbohydrate or if Applicant is claiming 20-80% by weight of at least one carbohydrate and at least 20-80% by weight of electrolytes. In the case of Claim 9, wherein Applicant is claiming "wherein the at least one amino acid is comprised in the soluble components of lactic yeast" in line 2, it is unclear as to what Applicant is claiming. What are the soluble components of lactic yeast? Is Applicant claiming that the amino acid is obtained from lactic yeast? Is Applicant claiming that the amino acid is found in lactic

yeast? In the case of Claim 11 wherein Applicant claims, "wherein the amino acid is glutamine and is in the range of up to 10% by weight", in lines 1 and 2, is Applicant claiming the amino acid is in a range of up to 10% by weight or is Applicant claiming that glutamine is in the range of at least 10% by weight? In the case of Claim 13 wherein Applicant claims, "wherein at least one of the salts comprised by the electrolytes and is at least one of the salts which will replace at least one of the salts lost by diarrhea" lines 1-3, is Applicant claiming that at least one of the electrolyte salts will replace the salt lost by diarrhea or is Applicant claiming that the salts are replaced by the electrolytes? The claim is poorly written and needs to be corrected to accurately reflect what Applicant is claiming. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

Claim 13 recites the limitation "the salts" in lines 2 and 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 22 contains the trademark/trade name "FD&C RED #40". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or

trade name. In the present case, the trademark/trade name is used to identify/describe a water extract of cinnamon and, accordingly, the identification/description is indefinite.

The term "natural vitamin E" in claim 23, line 2 is a relative phrase which renders the claim indefinite. The term "natural vitamin E " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Therefore, the lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 2-4 and 25 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. Applicant claims, "Use of a composition comprising: from 5-30% by weight of Isphagula Husk, from 1-20% by weight of at least one amino acid, and from 20-80% by weight of at least one carbohydrate and electrolytes for the preparation of a medicament for simultaneous or sequential use in treating a state of disorder on the intestinal system of monogastric animals, including human beings" as Claim 14, "Use of a composition comprising: from 5-30% by weight of Isphagula Husk, from 1-20% by weight of at least one amino acid, and from 20-80% by weight of at least one

carbohydrate and electrolytes for the preparation of a medicament for treating a state of disorder on the intestinal system of monogastric animals, including human beings" as Claim 15 and "Use of a composition comprising: from 5-30% by weight of an agent comprising Isphagula Husk, from 1-20% by weight of at least one amino acid, and from 20-80% by weight of at least one carbohydrate and electrolytes for the preparation of a medicament for restoring the epithelium layer of the intestines of mammals, including human beings" as Claim 16, and "Use of a composition of Claim 10 for manufacture of a medicament for treating diarrhoea" as Claim 25. It is unclear whether Applicant is claiming a method of using a composition comprising Isphagula husk, amino acids, at least one carbohydrate and electrolytes or if Applicant is claiming a method of making a composition comprising Isphagula husk, amino acids, at least one carbohydrate and electrolytes since no active steps of how to use the claimed product are recited. The claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). Therefore, the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5-8, 10, 11, 13, 16-19 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Bell et al. (A, US 6,365,176 B1).

Bell teaches a nutritional supplement comprising psyllium husk fiber (See column 5, lines 19-35) in an amount of 0.5 to 5 grams or in an amount of 0.5 grams to 11 grams (See column 5, lines 53-57), whey bran and oat bran (See column 5, lines 4 and 5), which reads on filler, fructose in an amount of 0.5 grams to 11 grams, more preferably 2 grams (See column 6, lines 7 and 8), which reads on carbohydrate, glutamine in an amount of 1 gram to 80 grams or 20 grams to about 40 grams (See column 10, lines 59-67), which reads on amino acid, sodium chloride and potassium chloride (See column 11, lines 15) and vitamin E (See column 11, line 22). Bell further teaches additional flavors, which reads on at least one taste corrigent, and coloring agents.

Therefore, the reference anticipates the claimed subject matter.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

> the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 5-8, 10, 11, 13-21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gjerlov (B, US Patent Number 5,038,396), in view of Simone (C, US Patent Number 5,397,786).

Gjerlov teaches a preparation for rehydrating monogastric animals, including human beings, suffering from diarrhea, wherein the composition comprises electrolytes, such as sodium chloride and potassium chloride (See column 3, lines 54-55), in an amount of 40-60% by weight (See column 4, lines 3 and 33), fibre (which is an alternative spelling of fiber) from dried, crushed seed coats of Plantgo ovata, which is synonymous with Isphagula Husk (See column 4, lines 22-26 and lines 42-66), in an amount of 20-70% by weight (See column 4, lines 31 and 32), fillers, such as fibrous wheat bran (See column 12, claims 8 and 9), taste corrigents and coloring agents (See abstract), such as pharmaceutically tolerable coloring agents (See column 3, line 63) in the form of a beverage (See column 5, lines 26-49). Please note that electrolytes, by definitions, replace salts lost by the body through excessive fluid loss (such as via vomiting, sweating, diarrhea, etc.).

Simone teaches a rehydration drink for people who work under severe conditions, are athletes and patients who exhibit dehydration from diarrhea or vomiting, comprising 1-35 milligrams of at least one carbohydrate, such as glucose (See column 2, lines 45-48, 64 and 65), electrolytes in an amount of 2 to 2500 milligrams, such as sodium chloride and potassium chloride (See column 3, lines 5 and 9), at least one ammonia neutralizer, in the form of an amino acid, in an amount of 0.1 to 750

milligrams, such as glutamine (See column 3, lines 21-28), and at least one antioxidant, such as vitamin E (See Abstract). Please note that electrolytes, by definitions, replace salts lost by the body through excessive fluid loss (such as via vomiting, sweating, diarrhea, etc.).

The teachings of Gjerlov are set forth above. Gjerlov does not teach a composition comprising Isphagula husk, at least one amino acid, at least one carbohydrate and electrolytes. Nor does Gjerlov teach a composition further comprising glutamine, glucose, or alpha tocopherol. However, at the time the invention was made, it would have been obvious to one of ordinary skill in the art and one would have been motivated and had a reasonable expectation of success to modify the composition taught by Gjerlov to provide the instantly claimed invention because at the time the invention was made, a composition for rehydrating monogastric animals, including human beings, suffering from diarrhea, comprising electrolytes, such as sodium chloride and potassium chloride, Isphagula Husk, fillers, such as fibrous wheat bran, taste corrigents and coloring agents, such as pharmaceutically tolerable coloring was known, as clearly taught by Gjerlov, as was a rehydration drink for people suffering from diarrhea comprising carbohydrates, such as glucose, electrolytes, such as sodium chloride and potassium chloride, amino acids, such as glutamine, and at least one antioxidant, such as vitamin E , as clearly taught by Simone.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art and one would have been motivated and had a reasonable expectation of success to modify the composition, to combine Isphagula husk, at least

one amino acid, at least one carbohydrate and electrolytes and further comprising glutamine, glucose, at least one filler, at least one taste corrigent and at least one coloring agent to provide the instantly claimed composition because at the time the invention was made, a composition for rehydrating monogastric animals, including human beings, suffering from diarrhea, comprising electrolytes, such as sodium chloride and potassium chloride, Isphagula Husk, fillers, such as fibrous wheat bran, taste corrigents and coloring agents, such as pharmaceutically tolerable coloring as was known as clearly taught by Gjerlov, as was a rehydration drink for people suffering from diarrhea comprising carbohydrates, such as glucose, electrolytes, such as sodium chloride and potassium chloride, amino acids, such as glutamine, and at least one antioxidant, such as vitamin E , as clearly taught by Simone. Therefore, it would have been obvious to one of ordinary skill in the art to modify the composition taught by Gjerlov to include the ingredients of the composition taught by Simone to provide the instantly claimed invention at the time the invention was made since both compositions were known to rehydrate humans suffering from diarrhea.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add any of the claimed ingredients in the making of the claimed composition because it is well known that its *prima facie* obvious to combine two or more ingredients, each of which is taught by the prior art, to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423,

426 (1971); *In re Crocketti*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based upon the beneficial teachings of the cited references, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at http://www.uspto.gov/ebc/index.html or 1-866-217-9197.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MICHELE FLOOD
PRIMARY EXAMINER

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October 27, 2006